DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

937142

Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097

November 4, 2002

WARNING LETTER
CIN-03-15201

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Loyie L. Allen, Owner
Breathe Easy Medical Equipment LLC
6524-B Old Lebanon Rd.
Campbellsville, KY 42718

Dear Mr. Allen:

The Food and Drug Administration conducted an inspection of your medical gas facility, located at the above address, on September 19,20, 24, & 26, 2002. This inspection covered your transfilling of Oxygen USP compressed gas. Oxygen USP is a drug as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Our inspection found significant deviations from the current Good Manufacturing Practices for drug products set forth in Title 21, Code of Federal Regulations, (21 CFR) Parts 210 and 211. These deviations cause your medical gases to be adulterated within the meaning of section 501(a)(2)(B) of the Act .

Specific observations made during the Inspection include:

1) Failure to assay each batch of Oxygen U.S.P. for identity and strength prior to release for distribution (21 CFR 211.165(a)). Specifically, it was determined that the transfilling operator does not know how to operate the oxygen analyzer and it has not been used for at least 3 ½ years. However, post-fill purity test values are being entered for each batch.

2) Failure to conduct prefill cylinder inspections in accordance with appropriate written procedures (21 CFR 211.84(d)(3)). Specifically, no odor test, vent procedures, or visual inspections for condition, color, valve and labeling are performed and documented.

3) Failure to document review and approval of production and control records by a responsible individual prior to release and shipment of medical gas (21 CFR 211.192).

4) Failure to establish and maintain production records documenting each significant step in the production and control of each batch of medical oxygen filled (21 CFR 211.188(b)). Specifically, batch records were not kept during the production period from 08/01/01 to 05/09/02.

5) Failure to calibrate your oxygen analyzer at suitable intervals to assure it complies with appropriate specifications for precision and accuracy (21 CFR 211.160(b)(4)). Specifically, you have not documented calibration of your oxygen analyzer since transfilling of medical oxygen was started at your firm.

6) Failure to establish appropriate written operating procedures for the production and process controls for repacking Oxygen U.S.P. (21 CFR 211.100(a)). Specifically, no written procedures have been established for transfilling, including assurance of correct fill volume; label controls; calibration, testing and release; handling of complaints; distribution controls and recall procedures.

7) Failure to assign a new lot number to each uninterrupted filling sequence (manifold load) of medical oxygen (21 CFR 211.130(c)). Specifically, lot numbers are only changed when source tanks (H cylinders) become empty or provide inadequate pressure to transfill.

8) Failure to assure that the appropriate volume of oxygen, as declared on the label, is added to each cylinder (21 CFR 211.101(a) & (b)). Specifically, filling temperature results, which are required to establish appropriate volume of fill, are not supported by actual accurately measured readings. The thermometer used during the inspection was broken and stuck at 150 degrees and had not been working for the last 3 ½ years.

9) Failure to calibrate pressure gauges, vacuum gauges and thermometers (21 CFR 211.68(a)). Specifically, there is no documentation that any of this equipment has ever been calibrated. The production thermometer was broken and had not worked in the last 3 ½ years according to the operator.

10) Failure to assure that each person engaged in the transfilling of medical gases has the education, training or experience to enable that person to perform their assigned function (21 CFR 211.25(a)). Specifically, there was no record that the filler had been trained in current good manufacturing practices. Furthermore, the operator was not able to demonstrate the calibration or the operation of the oxygen analyzer.

The above described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Until these violations are corrected, Federal agencies will be informed that FDA recommends against award of contracts for affected products.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in FDA initiating regulatory action without further notice. These include seizure and/or injunction.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations.

Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. We acknowledge receipt of your October 10, 2002 response letter, in which you agree to cease transfilling until you come into compliance. We expect a further response pertaining to specific corrective actions to be taken and the timeframes within which they will be completed

Your reply should be sent to the attention of Charles S. Price, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. Any questions regarding this letter may be directed to Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,

Carol A. Heppe
Acting District Director
Cincinnati District